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April 25, 2005

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Art Unit: 2171
Examiner: Patrick J.D. Santos
Conf. No.: 3929

Re: U.S. Patent Application No. 09/991,693 filed November 26, 2001
Inventor: Thomas P. BEALS
Title: Method for Organizing Laboratory Information in a Database
Atty. Dkt: 16517.321

Sir:

Transmitted herewith for appropriate action by the U.S. Patent and Trademark Office (PTO) are the following documents:

1. Appellant's Brief, with attached Appendix A; and
2. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

Authorization is hereby given to charge the statutory fee of \$500.00 for filing Appellants' Brief to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 16517.321. A duplicate copy of this letter is enclosed.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Appellants do not believe any additional fees are due in conjunction with this filing. However, if any fees are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 16517.321. A duplicate copy of this letter is enclosed.

Respectfully submitted,

Thomas E. Holsten (Reg. No. 46,098)

Enclosures



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:

Thomas P. BEALS

Appln. No.: 09/991,693

Filed: November 26, 2001

Title: **Method for Organizing Laboratory Information in a Database**

Confirmation No.: 3929

Art Unit: 2171

Examiner: Patrick J.D. Santos

Atty. Docket: 16517.321

APPELLANT'S BRIEF

Mail Stop Appeal Brief – Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-captioned patent application. A Notice of Appeal was filed on February 23, 2005. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter.

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

Appellant is unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 13 and 14 are pending. Claims 1-12 were cancelled without prejudice to or disclaimer of the subject matter claimed therein in an Amendment After Final filed February

23, 2005. Claims 13 and 14 stand finally rejected under 35 U.S.C. § 103. Appellant appeals all of the rejections of claims 13 and 14.

4. Status of Amendments

Subsequent to the Final Office Action mailed November 23, 2004 ("Final Action") in this case, an Amendment After Final Rejection (the "Amendment") was filed on February 23, 2005 canceling claims 1-12, without prejudice to or disclaimer of the underlying subject matter. In response to the Amendment, an Advisory Action was subsequently mailed by the U.S. Patent and Trademark Office on March 9, 2005 ("Advisory Action"), stating that "[f]or purposes of Appeal, the proposed amendment(s) will be entered...." *See*, Advisory Action mailed March 9, 2005.

5. Summary of Claimed Subject Matter

The claimed subject matter is directed to method for organizing information in a database in order to record information from an RNA transcript profiling laboratory procedure, comprising defining a set of container types, where the container types in the set of container types each have one or more positions capable of having content and where the set of container types comprises members selected from the group consisting of an Eppendorf tube, a 96 well plate, a transcript profiling array, a freezer, a data recording media screen, and a bitmap image of a data recording media screen; defining a set of operation types, where the set of operation types comprises members selected from the group consisting of printing arrays, reading out a data recording media screen, creation of a plate for PCR, and a robot run that transfers content from one container to another; defining a set of measurement types, where the set of measurement types comprises members selected from the group consisting of OD₆₀₀ of a bacterial plate, OD₂₆₀ of a DNA solution, intercalating agent quantitation of PCR product, agarose gel quantitation of PCR product, mRNA quantitation, and readout signal for each position in an array; defining a set of process types, where the set of

process types comprises members selected from the group consisting of incubating, PCR cycling, denaturing arrays, prepare probe from RNA, hybridize probe with array, incubate data recording media screens, and readout data recording screen; performing one more operations, where performing any one of the operations creates a new container with a unique identifier, and where the new container with a unique identifier is one of the container types in the set of container types; performing one or more processes on one or more of the new containers, where performing any one of the processes changes a state in one or more of the new containers; and, performing one or more measurements, where performing any one of the measurements results in associating data with content in one or more of the new containers. Specification at page 2, line 24 through page 3, line 5 and page 4, lines 28-29. A copy of the claims on appeal is attached hereto as Appendix A.

6. Grounds of Rejection to be Reviewed on Appeal

The sole ground of rejection to be reviewed in this Appeal is that pending claims 13 and 14 stand rejected under 35 U.S.C. § 103(a) for alleged obviousness.

7. Argument

A. Summary of Appellant's Position

The claimed methods and devices are non-obvious over the prior art. The claims are directed to methods for organizing information in a database in order to record information from an RNA transcript profiling procedure. The references cited by the Examiner do not disclose, teach or even suggest the claims of the present invention. Absent a disclosure, teaching or suggestion of each and every element of the claims, *i.e.*, methods for organizing information in a database in order to record information from an RNA transcript profiling procedure as presently claimed, the references cited by the Examiner does not obviate the present claims.

B. The Claimed Methods Are Not Obvious

Claims 13 and 14 stand “rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Greenbowe ‘865 and Brenner ‘440 in view of U.S. Patent No. 6,190,868 issued to Rothberg et al. (Hereafter Rothberg ‘868)” Final Action mailed March 3, 2004 (“Final Action”), at page 10.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined), considered in its entirety, must teach or suggest all of the claim limitations. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The teaching or suggestion to make the claimed combination must be found in the prior art, and not be based on Applicant’s disclosure. See M.P.E.P. §§2143.01 through 2143.03.

In a proper obviousness determination, the changes from the prior art must be evaluated in terms of the whole invention, including whether the prior art provides any teaching or suggestion to one of ordinary skill in the art to make the changes that would produce the claimed invention. See *In re Chu*, 36 U.S.P.Q.2d 1089, 1094 (Fed. Cir. 1995). This includes what could be characterized as simple changes. See, e.g., *In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984) (Although a prior art device could have been turned upside down, that did not make the modification obvious unless the prior art fairly suggested the desirability of turning the device upside down.).

Only when the prior art teaches or suggests the claimed invention does the burden fall on the applicant to rebut that *prima facie* case. See *In re Dillon*, 16 U.S.P.Q.2d 1897, 1901 (Fed. Cir. 1990) (in banc), *cert. denied*, 500 U.S. 904 (1991). However, a *prima facie* case of obviousness may be rebutted by showing that the art, in any material respect, teaches away from the claimed invention.

In this case, the Examiner alleges that:

Greenbowe teaches a method for organizing laboratory information, comprising:

- defining a set of container types, wherein container types in said set of container types each have one or more positions capable of having content...;
- defining a set of operation types...;
- defining a set of process types ...;
- performing one or more operations, wherein performing any one of said operations creates a new container with a unique identifier, and wherein said new container with a unique identifier is one of said container types in said set of container types...;
- performing one or more processes on one or more of said new containers, wherein performing any one of said processes changes a state in one or more of said new containers...; and
- performing one or more measurements, wherein performing one or more measurements results in associating data with content in one or more of said new containers....

Final Action at pages 10-11. The Examiner admits that “Greenbowe ‘865 does not explicitly teach a database in order to record information or application to an RNA transcript profiling laboratory procedure.” *Id.* at page 11. The Examiner alleges however that Brenner 440 teaches a database and that “Rothberg ‘868 teaches a method of identifying a nucleic acid sequence which includes: container types...; operation types...; measurement types...; and process types....” *Id.* at pages 11-12. The Examiner concludes that “[I]t would have been obvious for a person having ordinary skill in the art to combine the database of Brenner ‘440 to the chemistry laboratory simulator [of] Greenbowe ‘865.” *Id.* at page 12.

The Examiner further argues that the “nucleic acid sequence method of Rothberg ‘868 is a species of chemistry experiments” and that therefore the “method of Rothberg ‘868 lends

itself to the chemistry laboratory simulator of the Greenbowe '865 and Brenner '440 combination." *Id.*

Initially, Appellant respectfully disagrees with the Examiner's characterization of the art. By way of example, the Examiner asserts that "Greenbowe '865 teaches a method for organizing laboratory procedure information...." *Id.* at page 10. In this regard, Appellant notes that nowhere does Greenbowe disclose or suggest a method for organizing laboratory procedure data. Instead, Greenbowe provides an apparatus and methods for teaching science and engineering to a student using "simulations of experiments in science and engineering. Greenbowe '865 at col. 1, lines 61-64. In addition, the Examiner alleges that "Brenner '440 teaches a database." *Id.* at page 3. Applicant respectfully submits that Brenner teaches a device and methods for managing kitchen recipes. As such, it is respectfully submitted that the Examiner's conclusion of obviousness is based on improper reasoning and a mischaracterization of the art.

Even assuming *arguendo* that the combination is proper, the combination does not render the claimed invention obvious. Whatever else Greenbowe and Brenner disclose, they do not teach or suggest a method for organizing information in a database in order to record information from an RNA transcript profiling laboratory procedure. The Examiner has not pointed to any specific suggestion in any of the cited references that would lead one skilled in the art to combine the cited references to reach the presently claimed invention, for example, to record information from an RNA profiling laboratory procedure. It is impermissible hindsight to find it obvious for one skilled in the art to combine the various prior art references to reach the invention in the present application absent some suggestion or motivation in the prior art. Therefore, it would not be obvious to one of skill in the art, from reading Greenbowe, and Brenner, that one could obtain the methods of the present invention.

Moreover, the skilled artisan would not turn to Brenner to solve the problem of organizing information in a database in order to record information from an RNA transcript pro-

filing laboratory procedure. The Examiner alleges that Brenner is analogous art because “the system of Brenner ‘440 is directed to kitchen/cookbook recipes which are analogous to chemistry laboratory procedures....” *Id.* “In order to rely on a reference as a basis for rejection of an applicant’s invention, the reference must either be in the field of applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.” *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). *See also In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 23 USPQ2d 1058 (Fed. Cir. 1992). Appellant submits that Brenner is not analogous art. First, the Brenner reference is not in the Appellant’s field of endeavor. As the Examiner points out, the Brenner reference describes improved devices and methods for managing kitchen/cookbook recipes. This is a different field of endeavor from the methods for organizing information in a database in order to record information from an RNA transcript profiling laboratory procedure of the present invention.

Second, nor is Brenner reasonably pertinent to the particular problem that the present inventors faced. Brenner addresses the “need for a device which contains the advantages of cookbooks, including ease of use and portability into and around the kitchen, with the advantage of cookbook programs, including recipe searching and indexing and the ability to incorporate an unlimited number of recipes from different cuisines, recipes having different cooking skill levels and recipes from different meals.” Brenner ‘440 at col. 1, lines 43-49. A person faced with the problem of organizing information from an RNA transcript profiling procedure would not find the teachings of Brenner pertinent.

In sum, the Examiner’s conclusion of obviousness is based on improper hindsight reasoning using references not pertinent to the particular problem that the present inventors faced. “Impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” M.P.E.P. § 2142 at 2100-124. No suggestion to modify the cited references has been found in the cited references or pointed out to Appellant

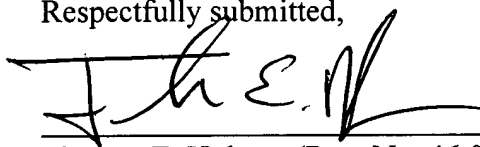
from the general knowledge of one of ordinary skill in the art. The references do not disclose or suggest a method for organizing information in a database in order to record information from an RNA transcript profiling laboratory procedure. As such, the cited references do not render the present claims obvious.

Accordingly, for at least the foregoing reasons, the rejection of claims 13 and 14 under 35 U.S.C. § 103 is improper and should be reversed.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,



Thomas E. Holsten (Reg. No. 46,098)
David R. Marsh (Reg. No. 41,408)

Date: April 25, 2005

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APPENDIX A
Claims as Pending

Claims 1-12. (Cancelled)

13. (Original) A method for organizing information in a database in order to record information from an RNA transcript profiling laboratory procedure, comprising:

defining a set of container types, wherein container types in said set of container types each have one or more positions capable of having content and wherein said set of container types comprises members selected from the group consisting of an Eppendorf tube, a 96 well plate, a transcript profiling array, a freezer, a data recording media screen, and a bitmap image of a data recording media screen;

defining a set of operation types, wherein said set of operation types comprises members selected from the group consisting of printing arrays, reading out a data recording media screen, creation of a plate for PCR, and a robot run that transfers content from one container to another;

defining a set of measurement types, wherein said set of measurement types comprises members selected from the group consisting of OD₆₀₀ of a bacterial plate, OD₂₆₀ of a DNA solution, intercalating agent quantitation of PCR product, agarose gel quantitation of PCR product, mRNA quantitation, and readout signal for each position in an array;

defining a set of process types, wherein said set of process types comprises members selected from the group consisting of incubating, PCR cycling, denaturing arrays, prepare

probe from RNA, hybridize probe with array, incubate data recording media screens, and readout data recording screen;

performing one more operations, wherein performing any one of said operations creates a new container with a unique identifier, and wherein said new container with a unique identifier is one of said container types in said set of container types;

performing one or more processes on one or more of said new containers, wherein performing any one of said processes changes a state in one or more of said new containers; and,

performing one or more measurements, wherein performing any one of said measurements results in associating data with content in one or more of said new containers.

14. (Original) A program storage device readable by a machine, tangibly embodying a program of instructions executable by a machine to perform method steps of claim 13 for organizing information obtained from RNA transcript profiling in a database.